Designation: ~~E2081 – 00 (Reapproved 2015)~~ E2081 – 22

Standard Guide for Risk-Based Corrective Action[1]

This standard is issued under the fixed designation E2081; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This guide provides guidance for the development of a Risk-Based Corrective Action (RBCA) program that integrates the sciences of ecological and human health risk-based decision making into the corrective action process. The RBCA provides a flexible, technically defensible framework for corrective action that is applicable to a wide range of sites and chemical(s) of concern. The framework incorporates a tiered analytical approach, applying increasingly complex levels of data collection and analysis as the user proceeds through the process. It provides a starting point for the integration of multiple regulatory programs into a site-wide corrective action activity and a technically defensible process for achieving "No Further Action." The successful implementation of the RBCA framework is dependent on an understanding by the user of the technical policy decisions that are critical to the risk management process and the identification and determination of these technical policy decisions prior to beginning the process (see 3.2.60). There are numerous technical policy decisions that must be made to implement the RBCA process, for example, defining data quality objectives, determining target risk levels and addressing resource protection. It is not the intent of this guide to define appropriate technical policy decisions. The RBCA process is not intended to replace existing regulatory programs, but rather to complement these programs. Regardless of whether a corrective action is specifically governed by a regulatory program, the user should consult the regulatory agency requirements to identify the appropriate technical policy decisions prior to implementing the RBCA process. The RBCA process encourages user-led initiatives and stakeholder involvement in both the development of the technical policy decisions and the RBCA program. It recognizes the diversity of sites and provides appendixes for possible applications and examples. The appendixes are provided for additional information and are not mandatory sections of this standard guide. ASTM standards are not federal or state regulations; they are consensus standards that can voluntarily be followed.

1. Scope

1.1 This is a guide for conducting risk-based corrective action (RBCA) at chemical release sites based on protecting human health and the environment. The RBCA is a consistent decision-making process for the assessment and response to chemical releases. Chemical release sites vary greatly in terms of complexity, physical and chemical characteristics, and in the risk that they may pose to human health and the environment. The RBCA process recognizes this diversity by using a tiered approach that integrates site assessment and response actions with human health and ecological risk assessment to determine the need for remedial action and to tailor corrective action activities to site-specific conditions and risks. The evaluations and methods used in the RBCA process begin with simple analyses in Tier 1 and move to more complex evaluations in either Tier 2 or Tier 3, as applicable. The process

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment, Risk Management and Corrective Action and is the direct responsibility of Subcommittee E50.04 on Corrective Action.

Current edition approved ~~April 1, 2015~~April 1, 2022. Published ~~May 2015~~May 2022. Originally approved in 1998. Last previous edition approved in ~~2010~~2015 as E2081-00 ~~(2010)~~(2015).~~ε1~~ DOI: ~~10.1520/E2081-00R5.~~10.1520/E2081-22.

of gathering and evaluating data is conducted in a scaled fashion. Consequently, only the data that are necessary for a particular tier's decision-making are collected at that tier.

1.2 This guide describes an approach for risk-based corrective action. It is intended to help direct and streamline the corrective action process and to complement but not to supersede federal, state and local regulations. It can be employed at sites where corrective action is being conducted including sites where there may not be a regulatory framework for corrective action, or where the user wishes to conduct corrective action such as sites in voluntary cleanup programs or under Brownfields initiatives. In addition, it can also be used as a unifying framework when several different agency programs affect the site. Furthermore, the user should be aware of the federal, state and local corrective action programs that are applicable for the site and, regardless of the program, federal, state and local agency approvals may be required to implement the processes outlined in this guide. Finally, regardless of whether a corrective action is specifically governed by a regulatory program, the user should consult the regulatory agency requirements to identify the appropriate technical policy decisions prior to implementing the RBCA process.

1.3 There are numerous technical policy decisions that must be made to implement the RBCA process, for example, defining data quality objectives, determining target risk levels, specifying the appropriate statistics and sample sizes for calculating exposure concentrations, selection of exposure assumptions, determining when and how to account for cumulative risks and additive effects among chemical(s) of concern and addressing resource protection. It is not the intent of this guide to define appropriate technical policy decisions. The user must identify the appropriate technical policy decisions.

1.4 The general performance standard for this guide requires that:

1.4.1 Technical policy decisions be identified before beginning the process,

1.4.2 Data and information collected during the RBCA process, including historical data as well as new data collected during the site assessment, will be relevant to and of sufficient quantity and quality to answer the questions posed by and the decisions to be made in the RBCA process,

1.4.3 Actions taken during the risk-based decision process will be protective of human health and the environment,

1.4.4 Applicable federal, state and local regulations will be followed (for example, waste management requirements, ground water designations, worker protection) and,

1.4.5 Remedial actions implemented will not result in higher risk levels than existed before taking actions.

1.5 ASTM standards are not federal or state regulations, they are consensus standards that can voluntarily be followed.

1.6 The RBCA process is not limited to a particular class of compounds. This guide is intended to be a companion to Guide E1739, and does not supersede that document for petroleum releases. If a release site contains a mixture of releases of petroleum and other chemicals, this guide should be followed.

1.7 The United States Environmental Protection Agency (USEPA) has developed guidance for human health risk evaluation (see Appendix ~~X8~~X9 for other resources). Many of the components of this guidance have been integrated into the RBCA framework. The science of ecological evaluation and the process by which the science is applied, however, are not as well defined and agreed upon as human health risk assessment. Therefore, the information provided in this guide for each tier evaluation for relevant ecological receptors and habitats is general. The user is referred to Appendix X5, which provides additional information regarding the development of a RBCA framework for protection of ecological resources.

1.8 The decision process described in this guide integrates exposure and risk assessment practices with site assessment activities and remedial action selection to ensure that the chosen actions are protective of human health and the environment. The following general sequence of events is prescribed in RBCA:

1.8.1 Perform an initial site assessment and develop the first iteration of the site conceptual ~~model.~~ model (see Guides E1689 and E3240 and ISO 21365:2019). If the information is sufficient to demonstrate that there are no complete or potentially complete exposure pathways, then no further action is warranted,

1.8.2 Evaluate the site (see definition of site 3.2.50) for response actions (multiple sites at a single facility may require different response actions and times),

1.8.3 Implement a response action that is appropriate for conditions found at the site during the site response action evaluation,

1.8.4 Define data requirements, develop data quality objectives, and perform a site assessment for the Tier 1 evaluation if the site conceptual model indicates that the tiered evaluation is appropriate,

1.8.5 Conduct an exposure pathway analysis to determine if relevant ecological receptors and habitats are present and if complete and potentially complete exposure pathways are present. If no relevant ecological receptors or habitats or complete and potentially complete exposure pathways exist, then no further action for relevant ecological receptors and habitats is warranted,

1.8.6 For potential human exposure pathways, identify the applicable Risk Based Screening Levels (RBSL) and for potential ecological exposure pathways, identify the applicable Relevant Ecological Screening Criteria (RESC). In addition, identify any Other Relevant Measurable Criteria (ORMC), as applicable. Collectively these are the Tier 1 corrective action goals for the site;

1.8.7 Compare site conditions to the Tier 1 corrective action goals determined to be applicable to the site;

1.8.8 If site conditions meet the corrective action goals for chemical(s) of concern then, no further action is warranted,

1.8.9 If site conditions do not meet corrective action goals for chemical(s) of concern then, one or more of the following actions is appropriate:

1.8.9.1 Further tier evaluation;

1.8.9.2 Implement interim remedial action;

1.8.9.3 Design and implement remedial action to achieve the corrective action goals.

1.8.10 Define Tier 2 data requirements, data quality objectives, collect additional site-specific information and update the site conceptual model, as necessary, if further tier evaluation is warranted,

1.8.11 Develop point(s) of demonstration and Tier 2 corrective action goals based on Site-Specific Target Levels (SSTL), Site-Specific Ecological Criteria (SSEC) or ORMC, where appropriate, for complete and potentially complete exposure pathways, including exposure pathways for which no RBSL, RESC or ORMC, as applicable, were determined;

1.8.12 Compare site conditions to the Tier 2 corrective action goals determined to be applicable to the site;

1.8.13 If site conditions meet corrective action goals for chemical(s) of concern, then no further action is warranted,

1.8.14 If site conditions do not meet corrective action goals for chemical(s) of concern then, one or more of the following actions is appropriate:

1.8.14.1 Further tier evaluation;

1.8.14.2 Implement interim remedial action;

1.8.14.3 Design and implement remedial action to achieve the corrective action goals.

1.8.15 Define Tier 3 data requirements, data quality objectives and collect additional site-specific information and update the site conceptual model, as necessary, if further tier evaluation is warranted,

1.8.16 Develop point(s) of demonstration and Tier 3 corrective action goals based on SSTL, SSEC, or ORMC, where appropriate;

1.8.17 Compare site conditions to the Tier 3 corrective action goals,

1.8.18 If site conditions meet corrective action goals for chemical(s) of concern, then no further action is warranted,

1.8.19 If site conditions do not meet corrective action goals for chemical(s) of concern, then one of the following actions is appropriate:

1.8.19.1 Implement interim remedial action to facilitate reassessment of the tier evaluation;

1.8.19.2 Design and implement remedial action to achieve the corrective action goals.

1.8.20 Develop and implement a monitoring plan based on the corrective action goals to validate the assumptions used for the tier evaluation and to demonstrate effectiveness of the remedial action, as applicable.

1.9 For chemical release sites currently in corrective action, the user should review information and data available for the site and determine the most appropriate entry point into the RBCA framework consistent with the general performance standards and sequence of events outlined in this guide.

1.10 *This Guide is Organized as Follows*—Section 2 lists referenced documents, Section 3 defines terminology used in this guide, Section 4 describes the significance and use of this guide, Section 5 is a summary of the tiered approach, and Section 6 presents the RBCA procedures in a step-by-step process. Appendix X1 provides guidance on developing technical policy decisions and building a RBCA program, Appendix X2 provides examples of chemical properties and effects data that may be useful for a RBCA evaluation, Appendix X3 provides EXAMPLE development of RBSL, Appendix X4 describes the use of predictive modeling, Appendix X5 provides an outline of the process of the ecological evaluation, Appendix X6 provides information about activity and use limitations, Appendix X7 includes illustrative examples of the application of the RBCA framework, Appendix X8 ~~and~~ addresses Per- and polyfluoroalkyl substances (*PFAS*). PFAS are synthetic chemicals that do not occur naturally in the environment. There are many different types of PFAS such as perfluorocarboxylic acids (for example, PFOA, sometimes called C8, and PFNA) and perfluorosulfonates (for example, PFOS and PFHxS), and Appendix ~~X8~~X9 includes references that may be helpful to the user.

NOTE 1—Appendix X8 references the Washington Department of Ecology's risk-based corrective action approach to PFAS as an example; numerous other states including Alaska, California, Colorado, Maine, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont have robust programs to address releases of PFAS to the environment. The ~~Appendixes~~appendixes are provided for additional information and are NOT included as mandatory sections of this guide.

1.11 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.12 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D5447 Guide for Application of a Numerical Groundwater Flow Model to a Site-Specific Problem
D5490 Guide for Comparing Groundwater Flow Model Simulations to Site-Specific Information
D5610 Guide for Defining Initial Conditions in Groundwater Flow Modeling
D5611 Guide for Conducting a Sensitivity Analysis for a Groundwater Flow Model Application
D5612 Guide for Quality Planning and Field Implementation of a Water Quality Measurement Program
D5718 Guide for Documenting a Groundwater Flow Model Application (Withdrawn 2022)[3]
~~D5880 Guide for Subsurface Flow and Transport Modeling (Withdrawn 2015)[3]~~
D6235 Practice for Expedited Site Characterization of Vadose Zone and Groundwater Contamination at Hazardous Waste Contaminated Sites
~~E978 Practice for Evaluating Mathematical Models for the Environmental Fate of Chemicals (Withdrawn 2002)[3]~~
E1527 Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process
~~E1599 Guide for Corrective Action for Petroleum Releases (Withdrawn 2002)[3]~~
E1689 Guide for Developing Conceptual Site Models for Contaminated Sites

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.
[3] The last approved version of this historical standard is referenced on www.astm.org.

E1739 Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites
E1903 Practice for Environmental Site Assessments: Phase II Environmental Site Assessment Process
~~E1912 Guide for Accelerated Site Characterization for Confirmed or Suspected Petroleum Releases (Withdrawn 2013)[3]~~
E1943 Guide for Remediation of Ground Water by Natural Attenuation at Petroleum Release Sites
E2091 Guide for Use of Activity and Use Limitations, Including Institutional and Engineering Controls
E2205/E2205M Guide for Risk-Based Corrective Action for Protection of Ecological Resources
E2531 Guide for Development of Conceptual Site Models and Remediation Strategies for Light Nonaqueous-Phase Liquids Released to the Subsurface
E3163 Guide for Selection and Application of Analytical Methods and Procedures Used during Sediment Corrective Action
E3164 Guide for Sediment Corrective Action – Monitoring
E3240 Guide for Risk-Based Corrective Action for Contaminated Sediment Sites
E3242 Guide for Determination of Representative Sediment Background Concentrations
E3248 Guide for NAPL Mobility and Migration in Sediment – Conceptual Models for Emplacement and Advection

2.2 *Other Referenced Documents*

California Office of Environmental Health Hazard Assessment, Toxicity Criteria Database, https://data.ca.gov/dataset/toxicity-criteria-database, May 2019
CRC CARE 2018, *Practitioner guide to risk-based assessment, remediation and management of PFAS site contamination*, CRC CARE Technical Report no. 43, CRC for Contamination Assessment and Remediation of the Environment, Newcastle, Australia.[4]
ISO 21365:2019 Soil quality -- Conceptual site models for potentially contaminated sites[5]
Pubchem databases; pubchem.ncbi.nlm.nih.gov
U.S. EPA, Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, EPA/240/B-06-01, 2006.[6]
U.S. EPA, Comptox Dashboard: https://comptox.epa.gov/dashboard
U.S. EPA, ECOTOX database; https://cfpub.epa.gov/ecotox/index.cfm
U.S. EPA, Recommendations from the EPA Groundwater Task Force, EPA 500-R-07-001, December 2007[6]
Washington Department of Ecology. Per- and Polyfluoroalkyl Substances. Chemical Action Plan. Publication 21-04-048. November 2021.[7]

3. Terminology

3.1 The reader should review the definitions presented here prior to reviewing the guide, as many of the terms included in this guide may have different meanings than the specific regulatory definitions within existing federal, state or local programs. The following terms are being defined to reflect their specific use in this guide. The user should not assume that these definitions replace existing regulatory definitions. Where the definition or use of a term in this guide differs from an existing regulatory definition or use, the user should address these differences prior to proceeding with the RBCA process.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *activity and use limitations*—Legal or physical restrictions or limitations on the use of, or access to, a site or facility to eliminate or minimize potential exposures to chemical(s) of concern, or to prevent activities that could interfere with the effectiveness of a remedial action, to ensure maintenance of site conditions that meet the corrective goals for chemical(s) of concern. ~~These legal or physical restrictions are intended to prevent adverse impacts to receptors and relevant ecological receptors and habitats that may be exposed to chemical(s) of concern. Activity and use limitations include both engineering and institutional controls.~~

3.2.1.1 *Discussion*—
These legal or physical restrictions are intended to prevent adverse impacts to receptors and relevant ecological receptors and habitats that may be exposed to chemical(s) of concern. Activity and use limitations include both engineering and institutional controls. (See Guide E2091.)

3.2.2 *additive effects*—refers to combined non-cancer effects of chemical(s) of concern with the same mechanism of action in a receptor.

[4] Available from CRC CARE, Newcastle University LPO PO Box 18. Callaghan NSW 2308 https://www.crccare.com/publications/technical-reports
[5] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.
[6] Available from United States Environmental Protection Agency (EPA), William Jefferson Clinton Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460, http://www.epa.gov.
[7] Available from Washington Department of Ecology, 300 Desmond Drive SE, Lacey, WA 98503 https://apps.ecology.wa.gov/publications/summarypages/2104048.html

3.2.3 *bio-availability*—a measure of the chemical(s) of concern in environmental media that is accessible to an organism for absorption.

3.2.4 *biodegradation*—Natural plant, animal, or microbial metabolism that results in the reduction of mass of a chemical(s) of concern.

3.2.5 *chemical release*—Any spill or leak or detection of concentrations of chemical(s) of concern in environmental media.

3.2.6 *chemical(s) of concern*—The specific compounds and their breakdown products that are identified for evaluation in the RBCA process. ~~Identification can be based on their historical and current use at a site, detected concentrations in environmental media and their mobility, toxicity, and persistence in the environment. Because chemical(s) of concern may be identified at many points in the RBCA process, including before any determination that they pose an unacceptable risk to human health or the environment, the term should not automatically be construed to be associated with increased or unacceptable risk.~~

3.2.6.1 *Discussion—*

Identification can be based on their historical and current use at a site, detected concentrations in environmental media and their mobility, toxicity, and persistence in the environment. Because chemical(s) of concern may be identified at many points in the RBCA process, including before any determination that they pose an unacceptable risk to human health or the environment, the term should not automatically be construed to be associated with increased or unacceptable risk.

3.2.7 *corrective action*—The sequence of actions that include site assessment and investigation, risk assessment, response actions, interim remedial action, remedial action, operation and maintenance of equipment, monitoring of progress, making no further action determinations and termination of the remedial action.

3.2.8 *corrective action goals*—concentration or other numeric values, physical condition or remedial action performance criteria that demonstrate that no further action is necessary to protect human health and the environment. ~~For example, these goals may include one or a combination of RBSL, SSTL, RESC, SSEC and ORMC chosen for source area(s), point(s) of demonstration and point(s) of exposure. The corrective action goals are specific to each Tier in the evaluation.~~

3.2.8.1 *Discussion—*

For example, these goals may include one or a combination of RBSL, SSTL, RESC, SSEC and ORMC chosen for source area(s), point(s) of demonstration and point(s) of exposure. The corrective action goals are specific to each Tier in the evaluation.

3.2.9 *cumulative risks*—refers to the combined carcinogenic risks from all exposure pathways for all chemicals for a receptor.

3.2.10 *direct exposure pathways*—An exposure pathway where the point of exposure is at the source, without a release to any other medium and without an intermediate biological transfer step.

3.2.11 *ecological evaluation*—A process for organizing and analyzing data, information, assumptions and uncertainties to evaluate the likelihood that adverse effects to relevant ecological receptors or habitats may occur or are occurring as a result of exposure to chemical(s) of concern.

3.2.12 *engineering controls*—Physical modifications to a site or facility to reduce or eliminate the potential for exposure to chemical(s) of concern (for example, slurry walls, capping, hydraulic controls for ground water, or point-of-use water treatment).

3.2.13 *exposure assessment*—The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration and route of exposure between a source area and a receptor.

3.2.14 *exposure pathway*—The course a chemical of concern takes from the source area(s) to a receptor or relevant ecological receptor and habitat. ~~An exposure pathway describes the mechanism by which an individual or population is exposed to a chemical of concern originating from a site. Each exposure pathway includes a source or release from a source of a chemical of concern, a point of exposure, an exposure route and the potential receptors or relevant ecological receptors and habitats. If the exposure point is not at the source, a transport or exposure medium, or both, (for example, air or water) are also included.~~

3.2.14.1 *Discussion—*

An exposure pathway describes the mechanism by which an individual or population is exposed to a chemical of concern originating from a site. Each exposure pathway includes a source or release from a source of a chemical of concern, a point of

exposure, an exposure route and the potential receptors or relevant ecological receptors and habitats. If the exposure point is not at the source, a transport or exposure medium, or both, (for example, air or water) are also included.

3.2.15 *exposure route*—The manner in which a chemical(s) of concern comes in contact with a receptor (for example, ingestion, inhalation, dermal contact).

3.2.16 *exposure scenario*—The description of the circumstances, including site properties and chemical properties, or the potential circumstances under which a receptor or a relevant ecological receptor or habitat could be in contact with chemical(s) of concern;

3.2.17 *facility*—The property containing the source of the chemical(s) of concern where a release has occurred. A facility may include multiple sources and therefore, multiple sites.

3.2.18 *guide*—a series of options or instructions that do not recommend a specific course of action.

3.2.19 *hazard index*—The sum of two or more hazard quotients for chemical(s) of concern or multiple exposure pathways to a particular receptor, or both.

3.2.20 *hazard quotient*—The ratio of the level of exposure of a chemical of concern over a specified time period to a reference dose for that chemical of concern derived for a similar exposure period.

3.2.21 *incremental carcinogenic risk levels*—The potential for incremental human carcinogenic effects, over background cancer occurrence levels, due to exposure to the chemical(s) of concern. This is the individual lifetime excess cancer risk.

3.2.22 *indirect exposure pathways*—An exposure pathway with at least one intermediate release to any media, or an intermediate biological transfer step, between the source and the point(s) of exposure (for example, chemical(s) of concern from soil through ground water to the point(s) of exposure).

3.2.23 *institutional controls*—A legal or administrative restriction on the use of, or access to a site or facility to eliminate or minimize potential exposure to a chemical(s) of concern (for example, restrictive covenants, restrictive zoning).

3.2.24 *interim remedial action*—The course of action taken to reduce migration of a chemical(s) of concern in its vapor, dissolved, or liquid phase, or to reduce the concentration of a chemical(s) of concern at a source area(s).

3.2.25 *maximum contaminant level (MCL)*—A standard for drinking water established by USEPA under the Safe Drinking Water Act which is the maximum permissible level of a chemical(s) of concern in water which is delivered to any user of a public water supply.

3.2.26 *natural attenuation*—The reduction in the concentration(s) of chemicals of concern in environmental media due to naturally occurring physical, chemical and biological processes (for example, diffusion, dispersion, adsorption, chemical degradation and biodegradation).

3.2.27 *non-aqueous phase liquids (NAPL)*—Chemicals that are insoluble or only slightly soluble in water that exist as a separate liquid phase in environmental media. They can be less dense or more dense than water.

3.2.28 *other relevant measurable criteria (ORMC)*—Parameters used to define corrective action goals for chemical(s) of concern. ~~The ORMC are concentration values, other numeric values, physical condition or performance criteria other than RBSL, RESC, SSTL or SSEC. Examples of ORMC are regulatory standards, consensus criteria, aesthetic criteria, and ground water protection criteria. Technical policy decisions regarding ORMC may exist, or may need to be made to determine the appropriate values, conditions or performance criteria that are used for the corrective action goals.~~

3.2.28.1 *Discussion—*
The ORMC are concentration values, other numeric values, physical condition or performance criteria other than RBSL, RESC, SSTL or SSEC. Examples of ORMC are regulatory standards, consensus criteria, aesthetic criteria, and ground water protection criteria. Technical policy decisions regarding ORMC may exist, or may need to be made to determine the appropriate values, conditions or performance criteria that are used for the corrective action goals.

3.2.29 *petroleum*—Includes crude oil or any fraction thereof that is liquid at standard conditions of temperature and pressure ~~(15.6°C~~(15.6 °C and 10 340 kg/m^{2}absolute). ~~The term includes petroleum-based substances comprised of a complex blend of hydrocarbons derived from crude oil through processes of separation, conversion, upgrading, and finishing, (for example, motor fuels, jet fuels, lubricants, petroleum solvents, used oils).~~

3.2.29.1 *Discussion—*
The term includes petroleum-based substances comprised of a complex blend of hydrocarbons derived from crude oil through processes of separation, conversion, upgrading, and finishing, (for example, motor fuels, jet fuels, lubricants, petroleum solvents, used oils).

3.2.30 *point(s) of demonstration*—A location(s) selected between the source area(s) and the potential point(s) of exposure where corrective action goals are met.

3.2.31 *point(s) of exposure*—The point(s) at which an individual or population may come in contact with a chemical(s) of concern originating from a site.

3.2.32 *potentially complete exposure pathway*—A situation with a reasonably likely chance of occurrence in which a receptor or relevant ecological receptor or habitat may become directly or indirectly exposed to the chemical(s) of concern.

3.2.33 *practice*—a definitive procedure for performing one or more specific operations or functions that does not produce a test result.

3.2.34 *probabilistic evaluation*—A modeling procedure used to evaluate the uncertainty surrounding a probability distribution when the result depends on a number of factors, each of which has its own variability and uncertainty.

3.2.35 *qualitative ecological screening evaluation*—A process conducted as part of the Tier 1 evaluation wherein relevant ecological receptors and habitats and exposure pathways are identified. ~~The necessary information can be collected as part of the data gathering activities during the initial site assessment or the Tier 1 site assessment (6.3.2 and 6.3.3). Within Tier 1, this screening-level information, which is typically qualitative, may be used to evaluate potential exposure pathways to relevant ecological receptors and habitats and to identify potential chemical(s) of concern. If available, generic, non-site-specific ecological criteria and guidelines (3.2.42) may be used to further evaluate complete and potentially complete exposure pathways.~~

3.2.35.1 *Discussion—*
The necessary information can be collected as part of the data gathering activities during the initial site assessment or the Tier 1 site assessment (6.3.2 and 6.5.1). Within Tier 1, this screening-level information, which is typically qualitative, may be used to evaluate potential exposure pathways to relevant ecological receptors and habitats and to identify potential chemical(s) of concern. If available, generic, non-site-specific ecological criteria and guidelines (3.2.42) may be used to further evaluate complete and potentially complete exposure pathways.

3.2.36 *qualitative risk analysis*—A non-quantitative evaluation of the potential risks at a site as determined by the potential exposure pathways and receptors based on known or reasonably available information.

3.2.37 *reasonable maximum exposure (RME)*—The highest exposure that is reasonably expected to occur at a site. RME's are estimated for individual exposure pathways or a combination of exposure pathways.

3.2.38 *reasonably anticipated future use*—Future use of a site or facility which can be predicted with a reasonably high degree of certainty given historical use, current use, and local government planning and zoning.

3.2.39 *receptors*—The persons that are or may be affected by a release. (see relevant ecological receptors and habitats, 3.2.41, for non-human receptor definition).

3.2.40 *reference dose*—A toxicity value for evaluating potential non-carcinogenic effects in humans resulting from exposure to a chemical(s) of concern.

3.2.41 *relevant ecological receptors and habitats*—The ecological resources that are valued at the site. ~~Because of the variety of ecological resources that may be present, focusing upon those relevant to a site is an important part of the problem formulation~~

~~phase of ecological evaluation. Identification of relevant ecological receptors and habitats is dependent upon site-specific factors and technical policy decisions. Examples may include species or communities afforded special protection by law or regulation; recreationally, commercially or culturally important resources; regionally or nationally rare communities; communities with high aesthetic quality; and habitats, species or communities that are important in maintaining the integrity and bio-diversity of the environment.~~

3.2.41.1 *Discussion—*

Because of the variety of ecological resources that may be present, focusing upon those relevant to a site is an important part of the problem formulation phase of ecological evaluation. Identification of relevant ecological receptors and habitats is dependent upon site-specific factors and technical policy decisions. Examples may include species or communities afforded special protection by law or regulation; recreationally, commercially or culturally important resources; regionally or nationally rare communities; communities with high aesthetic quality; and habitats, species or communities that are important in maintaining the integrity and bio-diversity of the environment.

3.2.42 *relevant ecological screening criteria (RESC)*—Generic, non-site specific ecological criteria or guidelines that are determined to be applicable to relevant ecological receptors and habitats, exposure pathways and site conditions utilized during the Tier 1 evaluation. ~~These may include chemical concentrations, biological measures or other relevant generic criteria consistent with the technical policy decisions.~~

3.2.42.1 *Discussion—*

These may include chemical concentrations, biological measures or other relevant generic criteria consistent with the technical policy decisions.

3.2.43 *remedial action*—Activities conducted to reduce or eliminate current or potential future exposures to receptors or relevant ecological receptors and habitats. ~~These activities include monitoring, implementing activity and use limitations and designing and operating clean-up equipment. Remedial action includes activities that are conducted to reduce sources of exposures to meet corrective action goals, or sever exposure pathways to meet corrective action goals.~~

3.2.43.1 *Discussion—*

These activities include monitoring, implementing activity and use limitations and designing and operating clean-up equipment. Remedial action includes activities that are conducted to reduce sources of exposures to meet corrective action goals, or sever exposure pathways to meet corrective action goals.

3.2.44 *response action*—An immediate course of action, including monitoring, abatement or containment measures to mitigate known or potential hazards to human health, safety and the environment, taken before interim remedial action or remedial action.

3.2.45 *response action evaluation*—A qualitative analysis of a site, based on known or readily available information, to identify the need for and urgency of response actions and the need for further information gathering. The analysis is also used to identify appropriate early risk reduction steps.

3.2.46 *risk*—The potential for, or probability of, an adverse effect. These may be expressed qualitatively or quantitatively.

3.2.47 *risk assessment*—An analysis of the potential for adverse effects on receptors and relevant ecological receptors and habitats caused by a chemical(s) of concern from a site. ~~The risk assessment activities are the basis for the development of corrective action goals and determination of where interim remedial actions, remedial action or a combination of actions are required.~~

3.2.47.1 *Discussion—*

The risk assessment activities are the basis for the development of corrective action goals and determination of where interim remedial actions, remedial action or a combination of actions are required.

3.2.48 *risk reduction*—The lowering or elimination of the level of risk posed to human health or the environment through, response actions, interim remedial actions, remedial action or a combination of actions.

3.2.49 *risk-based screening level/screening levels (RBSL)*—Non-site-specific human health risk-based values for chemical(s) of concern that are protective of human health for specified exposure pathways utilized during the Tier 1 evaluation.

3.2.50 *site*—The area(s) defined by the likely physical distribution of the chemical(s) of concern from a source area. ~~A site could be an entire property or facility, a defined area or portion of a facility or property or multiple facilities or properties. One facility may contain multiple sites. Multiple sites at one facility may be addressed individually or as a group.~~

3.2.50.1 *Discussion—*

A site could be an entire property or facility, a defined area or portion of a facility or property or multiple facilities or properties. One facility may contain multiple sites. Multiple sites at one facility may be addressed individually or as a group.

3.2.51 *site assessment*—A characterization of a site through an evaluation of its physical and environmental context (for example, subsurface geology, soil properties and structures, hydrology, and surface characteristics) to determine if a release has occurred, the levels of the chemical(s) of concern in environmental media, and the likely physical distribution of the chemical(s) of concern. ~~As an example, the site assessment collects data on soil, ground water and surface water quality, land and resource use, potential receptors, and potential relevant ecological receptors and habitats, and generates information to develop a site conceptual model and to support risk-based decision-making. The user is referred to Guides E1912 and D6235 and other references in Appendix X8 for more information.~~

3.2.51.1 *Discussion*—

As an example, the site assessment collects data on soil, ground water and surface water quality, land and resource use, potential receptors, and potential relevant ecological receptors and habitats, and generates information to develop a site conceptual model and to support risk-based decision-making. The user is referred to Guides D6235 and E1903 and other references in Appendix X9 for more information.

3.2.52 *site conceptual model*—The integrated representation of the physical and environmental context, the complete and potentially complete exposure pathways and the potential fate and transport of chemical(s) of concern at a site. ~~The site conceptual model should include both the current understanding of the site and the understanding of the potential future conditions and uses for the site. It provides a method to conduct the exposure pathway evaluation, inventory the exposure pathways evaluated, and determine the status of the exposure pathways as incomplete, potentially complete or complete.~~

3.2.52.1 *Discussion*—

The site conceptual model (sometimes called conceptual site model) should include both the current understanding of the site and the understanding of the potential future conditions and uses for the site. It provides a method to conduct the exposure pathway evaluation, inventory the exposure pathways evaluated, and determine the status of the exposure pathways as incomplete, potentially complete or complete. The *user* is referred to Guides E1689, E2531, E3248, and ISO 21365:2019

3.2.53 *site conditions*—A general description of a site's chemical, physical or biological characteristics that relate to potential exposures to receptors or relevant ecological receptors and habitats.

3.2.54 *site-specific*—Activities, information and data unique to a particular site.

3.2.55 *site-specific ecological criteria (SSEC)*—Risk-based qualitative or quantitative criteria for relevant ecological receptors and habitats identified for a particular site under the Tier 2 or Tier 3 evaluations. ~~These may include chemical concentrations, biological measures or other relevant generic criteria consistent with the technical policy decisions. SSEC may be revised as data are obtained that better describe the conditions and the relevant ecological receptors and habitats.~~

3.2.55.1 *Discussion*—

These may include chemical concentrations, biological measures or other relevant generic criteria consistent with the technical policy decisions. SSEC may be revised as data are obtained that better describe the conditions and the relevant ecological receptors and habitats.

3.2.56 *site-specific target levels (SSTL)*—Risk-based values for chemical(s) of concern that are protective of human health for specified exposure pathways developed for a particular site under the Tier 2 or Tier 3 evaluations.

3.2.57 *source area(s)*—The source area(s) is defined as the location of non-aqueous phase liquid (NAPL) chemical, the locations of highest soil or ground water concentrations of the chemical(s) of concern or the location releasing the chemical(s) of concern.

3.2.58 *stakeholders*—Individuals, organizations or other entities that directly affect or are directly affected by the corrective action. ~~Stakeholders include, but are not limited to, owners, buyers, developers, lenders, insurers, government agencies and community members and groups.~~

3.2.58.1 *Discussion*—

Stakeholders include, but are not limited to, owners, buyers, developers, lenders, insurers, government agencies and community members and groups.

3.2.59 *standard*—As used in ASTM, a document that has been developed and established within the consensus principles of the Society and that meets the approval requirements of ASTM procedures and regulations.

3.2.60 *technical policy decisions*—The choices specific to the user that are necessary to implement the Risk-Based Corrective Action framework described in this guide at a particular site. ~~The decisions involve regulatory policies, value judgments, different stakeholder decisions and using professional judgment to evaluate available information, therefore, there may be more than one scientifically supportable answer for any particular technical policy decision. The choices represent different approaches. The user should consult the regulatory agency requirements to identify the appropriate technical policy decisions prior to implementing the RBCA process. Examples of technical policy decisions are, data quality objectives, target risk levels, land use, ground water use, natural resource protection, relevant ecological receptors and habitats, stakeholder notification and involvement and exposure factors.~~

3.2.60.1 *Discussion—*

The decisions involve regulatory policies, value judgments, different stakeholder decisions and using professional judgment to evaluate available information, therefore, there may be more than one scientifically supportable answer for any particular technical policy decision. The choices represent different approaches. The user should consult the regulatory agency requirements to identify the appropriate technical policy decisions prior to implementing the RBCA process. Examples of technical policy decisions are, data quality objectives, target risk levels, land use, ground water use, natural resource protection, relevant ecological receptors and habitats, stakeholder notification and involvement and exposure factors.

3.2.61 *Tier 1 Evaluation*—A risk-based analysis utilizing non-site-specific corrective action goals for complete and potentially complete direct and indirect human exposure pathways and qualitative ecological screening evaluation for complete and potentially complete exposure pathways for relevant ecological receptors and habitats. ~~The non-site-specific corrective action goals developed for human exposure pathways are based on conservative assumptions (for example, exposure factors, fate and transport parameters) and methodologies (for example, algorithms, analytical models) to estimate the non-site-specific values. The Tier 1 exposure pathways for human receptors assume that the receptor and the source are located in the same location. A qualitative ecological screening evaluation is conducted that may be combined with RESC to evaluate the potential exposures to relevant ecological receptors and habitats. The Tier 1 evaluation for some chemical(s) of concern or exposure pathways may also be based on comparison of site conditions to ORMC. The non-site-specific corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.~~

3.2.61.1 *Discussion—*

The non-site-specific corrective action goals developed for human exposure pathways are based on conservative assumptions (for example, exposure factors, fate and transport parameters) and methodologies (for example, algorithms, analytical models) to estimate the non-site-specific values. The Tier 1 exposure pathways for human receptors assume that the receptor and the source are located in the same location. A qualitative ecological screening evaluation is conducted that may be combined with RESC to evaluate the potential exposures to relevant ecological receptors and habitats. The Tier 1 evaluation for some chemical(s) of concern or exposure pathways may also be based on comparison of site conditions to ORMC. The non-site-specific corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.

3.2.62 *Tier 2 Evaluation*—A risk-based analysis that involves an incremental refinement of the Tier 1 methodology to develop site-specific corrective action goals. ~~The Tier 2 evaluation for human exposure pathways may include developing statistically representative concentrations of chemical(s) of concern for comparison to the Tier 1 corrective action goals, back-calculating SSTL by applying the direct exposure pathway corrective action goals established under a Tier 1 evaluation at site-specific determined point(s) of exposure, developing SSTL for potential indirect exposure pathways at point(s) of exposure using site-specific conditions and the Tier 1 methodology, or developing SSTL for complete or potentially complete exposure pathways using site-specific conditions for which no RBSL were developed in Tier 1, or the evaluation may employ a combination of alternatives. For relevant ecological receptors and habitats, the Tier 2 evaluation may involve additional qualitative or quantitative analyses. The Tier 2 evaluation for some chemical(s) of concern and exposure pathways may also be based on comparison of site conditions to ORMC. The corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.~~

3.2.62.1 *Discussion—*

The Tier 2 evaluation for human exposure pathways may include developing statistically representative concentrations of chemical(s) of concern for comparison to the Tier 1 corrective action goals, back-calculating SSTL by applying the direct exposure pathway corrective action goals established under a Tier 1 evaluation at site-specific determined point(s) of exposure, developing SSTL for potential indirect exposure pathways at point(s) of exposure using site-specific conditions and the Tier 1 methodology, or developing SSTL for complete or potentially complete exposure pathways using site-specific conditions for which no RBSL were developed in Tier 1, or the evaluation may employ a combination of alternatives. For relevant ecological receptors and habitats, the Tier 2 evaluation may involve additional qualitative or quantitative analyses. The Tier 2 evaluation for some

chemical(s) of concern and exposure pathways may also be based on comparison of site conditions to ORMC. The corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.

3.2.63 *Tier 3 Evaluation*—A risk-based analysis that involves a significant incremental effort over the Tier 2 evaluation to develop site-specific corrective action goals. ~~The Tier 3 evaluation for human exposure pathways typically uses advanced exposure assessment, toxicity and risk assessment techniques (for example, probabilistic exposure assessment methods, use of bio-availability data, use of advanced fate and transport modeling) allowing maximum flexibility to develop SSTL for potential direct and indirect exposure pathways at the point(s) of exposure based on site-specific conditions. A Tier 3 evaluation for relevant ecological receptors and habitats is typically more quantitative in nature and uses more site-specific data than previous tiers. The Tier 3 evaluation for some chemical(s) of concern and exposure pathways may also be based on comparison of site conditions to ORMC. The corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.~~

3.2.63.1 *Discussion—*

The Tier 3 evaluation for human exposure pathways typically uses advanced exposure assessment, toxicity and risk assessment techniques (for example, probabilistic exposure assessment methods, use of bio-availability data, use of advanced fate and transport modeling) allowing maximum flexibility to develop SSTL for potential direct and indirect exposure pathways at the point(s) of exposure based on site-specific conditions. A Tier 3 evaluation for relevant ecological receptors and habitats is typically more quantitative in nature and uses more site-specific data than previous tiers. The Tier 3 evaluation for some chemical(s) of concern and exposure pathways may also be based on comparison of site conditions to ORMC. The corrective action goals for complete and potentially complete exposure pathways are compared to site conditions to determine if further corrective action is warranted.

3.2.64 *user*—An individual or group involved in the RBCA process including owners, operators, regulators, UST fund managers, federal government case managers, attorneys, consultants, legislators and other stakeholders. ~~Two specific cases of users are envisioned. The first is the individual or group addressing a site or sites under the circumstances where there is no specific agency program or there are multiple agency programs applicable to their project. The second is a regulatory agency that is developing a comprehensive corrective action program.~~

3.2.64.1 *Discussion—*

Two specific cases of users are envisioned. The first is the individual or group addressing a site or sites under the circumstances where there is no specific agency program or there are multiple agency programs applicable to their project. The second is a regulatory agency that is developing a comprehensive corrective action program.

3.3 *Acronynms and Abbreviations:*

3.3.1 *COC*—chemicals of concern

3.3.2 *ITRC*—Interstate Technology and Regulatory Council

3.3.3 *ORMC*—other relevant measurable criteria

3.3.4 *PFAS*—Per- and polyfluoroalkyl substances

3.3.5 *PFHxS*—perfluorohexane sulfonate, perfluorohexane sulfonic acid

3.3.6 *PFNA*—perfluorononoate, perfluorononanoic acid

3.3.7 *PFOA*—perfluorooctanoate, perfluorooctanoic acid

3.3.8 *PFOS*—perfluorooctane sulfonate, perfluorooctane sulfonic acid

3.3.9 *RBCA*—-Risk-Based Corrective Action

3.3.10 *RBSL*—Risk-Based Screening Level

3.3.11 *RESC*—relevant ecological screening criteria

3.3.12 *SSEC*—site-specific ecological criteria

3.3.13 *SSTL*—site-specific target levels

3.3.14 *USEPA*—United States Environmental Protection Agency

4. Significance and Use

4.1 The risk-based corrective action (RBCA) process presented in this guide is a consistent, streamlined decision process for selecting corrective actions at chemical release sites.

4.2 Risk assessment is a developing science. The scientific approach used to develop the RBSL and SSTL may vary by regulatory agency and by user due to regulatory requirements, guidance and use of alternative scientifically-based methods.

4.3 Activities described in this guide should be conducted by persons familiar with current site characterization techniques, remedial action science and technology, current human health risk and exposure assessment methodologies, toxicology, and current ecological evaluation methodologies.

4.4 In order to properly apply the RBCA process, the user should **AVOID** the following:

4.4.1 Prescribing Tier 1 RBSL or RESC as remedial action standards for all sites rather than screening levels,

4.4.2 Limiting use of the RBCA process to Tier 1 evaluation only and not continuing with Tier 2 or Tier 3 analyses for sites where further tier evaluation is appropriate,

4.4.3 Placing arbitrary time constraints on the corrective action process; for example, requiring that Tiers 1, 2, and 3 be completed within time periods that do not reflect the actual urgency of and risks posed by the site,

4.4.4 Using the RBCA process only when active remedial action is not technically feasible, rather than as a process that is applicable during all phases of corrective action,

4.4.5 Conducting active remedial action to achieve only technology-based remedial limits (for example, asymptotic levels) prior to determining applicable corrective action goals,

4.4.6 Using predictive modeling that is not supported by available data or knowledge of site conditions,

4.4.7 Limiting remedial action options to a single class of remedial actions for all ~~sites,~~sites (for example Guide E1943),

4.4.8 Using unjustified or inappropriate exposure factors,

4.4.9 Using unjustified or inappropriate toxicity parameters,

4.4.10 Failing to consider cumulative risks and additive effects when evaluating multiple chemicals,

4.4.11 Excluding the evaluation of options for activity and use limitations, point(s) of exposure, point(s) of demonstration, sequencing remedial action activities at multiple sites on the same facility, or risk levels,

4.4.12 Excluding the maintenance and monitoring of activity and use limitations,

4.4.13 Failing to consider the long-term effectiveness and reliability of potential remedial action options,

4.4.14 Failing to evaluate potential risks to the public, to workers and to relevant ecological receptors and habitats that may be created by proposed remedial actions or assessment methods and

4.4.15 Continuing monitoring or remedial action at sites that have achieved the corrective action goals (unless monitoring is

specifically required for an activity and use limitation or another regulatory requirement). Achievement of corrective action goals is predicated on sufficient monitoring to substantiate the site conditions.

4.5 The RBCA process described in this guide includes several features that are only examples of standardized approaches to addressing the objectives of the particular activity, for example, the response action evaluation table and the exposure scenario evaluation flowchart. These elements should be customized by the user based on the constraints of the site or group of sites being addressed and the appropriate technical policy decisions. The objectives of the analyses are identified in this guide.

5. A Tiered Approach to Risk-Based Corrective Action (RBCA)

5.1 Risk-based corrective action is the integration of site assessment, remedial action selection, and monitoring with appropriate risk and exposure assessment practices. This creates a process by which corrective action decisions are made in a consistent manner that is protective of human health and the environment. Prior to implementing the RBCA process, the user must identify the relevant technical policy decisions appropriate for the site (see 1.2, 1.3 and Appendix X1). The user should also identify the appropriate stakeholder notification and involvement process to provide information and to collect input during the implementation of the RBCA process.

5.2 The RBCA process is implemented in a tiered approach, involving increasingly sophisticated levels of data collection and analysis as the user proceeds through the tiers. At each further tier of evaluation, the assumptions of earlier tiers are replaced with additional site-specific data and information.

5.3 There is some degree of uncertainty associated with all risk estimates and site assessments. In the RBCA process it is necessary for the user to address uncertainty through the level of conservatism applied to each tier. As the user moves through the tier evaluation process, the level of conservatism should decrease as the uncertainty decreases. The uncertainty should be clearly articulated during each tier of evaluation. The analysis of uncertainty allows the user to determine if the information obtained is adequate to make a decision. As the user proceeds to higher tiers, the knowledge gained about the site is used to tailor the degree of investigation needed, as explained in the following sections. In some cases, after completion of the Tier 1 evaluation, the user may find it appropriate for some exposure pathways to proceed directly to a Tier 3 evaluation. As contemplated here, the results of all of the completed tiers of analyses would be compiled into one RBCA report at the end of the evaluation. Reporting requirements and approvals must be determined based on the particular federal, state and local programs that apply to the site.

6. Risk-Based Corrective Action (RBCA) Procedures

6.1 The sequence of principal tasks and decisions associated with the RBCA process are outlined on the flowcharts shown in Fig. 1 and Fig. 2. Each of these actions and decisions is discussed as follows. Prior to implementing these actions, the user should identify the appropriate stakeholder notification and involvement process to provide information and to collect input during the implementation of the RBCA process. Information is gathered in the initial site assessment to develop the site conceptual model.

6.2 *Initial Site Assessment*—The initial site assessment is a planning and scoping activity to develop the site conceptual model, (for example, identifying potential transport pathways and potential receptors) based on the initial understanding of the site. The planning and scoping activity is a critical part of implementing the technical policy decisions due to the potential complexity of human and ecological exposure pathways. This is especially important for ecological issues due to the variety of relevant ecological receptors and habitats. Information collected during the initial site assessment may identify incomplete exposure pathways that may eliminate the need for any further evaluation of one or more exposure pathways or the site. For example, some regulatory agencies specify processes to define incomplete exposure pathways or define minimum criteria, threshold quantities or concentrations of a chemical release as an exclusion from or entry to a further RBCA analysis for a site. If the information is sufficient to demonstrate that there are no complete or potentially complete exposure pathways, then no further action is warranted. If minimum criteria, threshold quantities or concentrations that define exclusion from a RBCA analysis are available and site conditions meet these criteria, thresholds or concentrations, as applicable, then no further action is warranted for the site.

6.2.1 The initial site assessment should include a review of known or reasonably available information on:

6.2.1.1 Appropriate regulatory requirements;

6.2.1.2 Historical site activities, past releases and prior site assessment information to identify potential chemical(s) of concern, sources of the chemical(s) of concern, source area(s), human receptors and relevant ecological receptors and habitats, and fate and transport mechanisms;

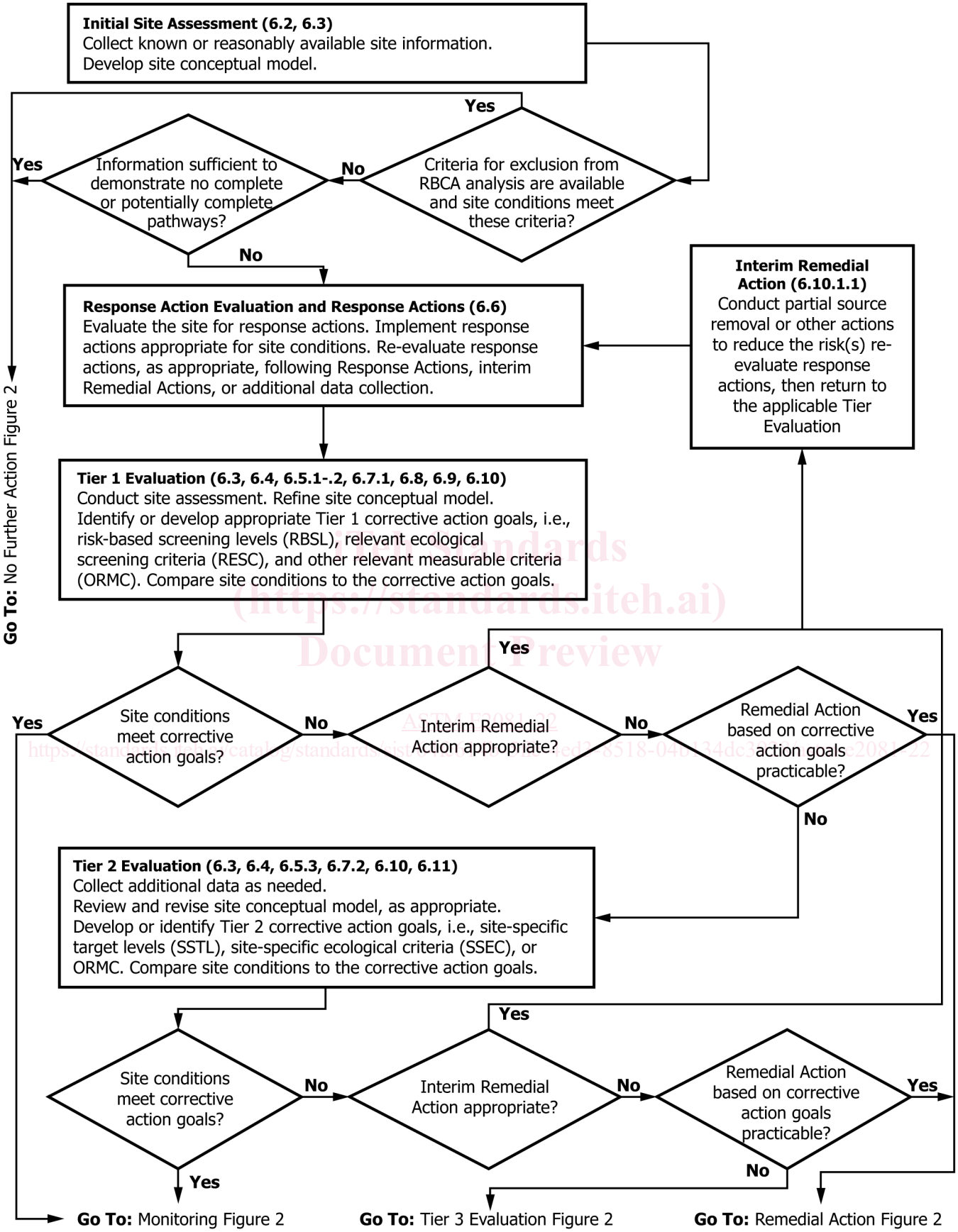

FIG. 1 RBCA Flowchart (After E1739-95)